

CLAIMS

What is claimed is:

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1. An apparatus for preparing a macromolecule sample, comprising:
a hydraulic system designed to separate a macromolecule from a mixture
that also includes larger and smaller components; and
a controller operably coupled to the hydraulic system and including
executable instructions to convert and execute operational input to
control the hydraulic system in a manner for preparing the macromolecule
sample.

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2. The apparatus according to Claim 1 wherein the executable instructions are
compiled software.

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3. The apparatus according to Claim 1 wherein the executable instructions are
unchangeable.

4. The apparatus according to Claim 1 wherein the executable instructions conform
to a known industry standard.

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5. The apparatus according to Claim 1 wherein the operational input includes
declarative software instructions.

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6. The apparatus according to Claim 1 wherein the executable instructions include
instructions to interpret program instructions.

7. The apparatus according to Claim 1 wherein the operational input is modifiable

independent of the executable instructions.

8. The apparatus according to Claim 1 wherein the controller includes an interface to receive the operational input from an external system.
- 5 9. The apparatus according to Claim 8 wherein the external system is coupled to the interface via a network.
- 10 10. The apparatus according to Claim 1 wherein:
the hydraulic system includes multiple devices addressable by the controller; and
the executable instructions include correspondence between predetermined indicators in the operational input and the multiple devices.
- 15 11. The apparatus according to Claim 1 wherein the executable instructions include instructions to detect errors in the operational input.
12. The apparatus according to Claim 1 wherein the hydraulic system includes:
at least one rough filter and at least one fine filter; and
20 a pump and at least one valve.
13. A method for preparing a macromolecule sample, comprising:
separating a macromolecule from a mixture that also includes larger and smaller components; and
25 converting and executing operational input to control the separating of the macromolecule in a manner for preparing the macromolecule sample.
14. The method according to Claim 13 wherein converting and executing the operational input includes executing executable instructions.

15. The method according to Claim 14 wherein the executable instructions are compiled software.
- 5 16. The method according to Claim 14 wherein the executable instructions are unchangeable.
17. The method according to Claim 14 wherein the executable instructions conform to a known industry standard.
- 10 18. The method according to Claim 13 wherein the operational input includes declarative software instructions.
19. The method according to Claim 13 wherein converting the operational input includes interpreting program instructions.
- 15 20. The method according to Claim 13 wherein the converting and executing is performed by executable instructions and the operational input is modifiable independent of the executable instructions.
- 20 21. The method according to Claim 13 further including receiving the operational input from an external system.
22. The method according to Claim 21 wherein receiving the operational input includes communicating across a network.
- 25 23. The method according to Claim 13 wherein converting and executing the operational input includes determining correspondence between predetermined indicators in the operational input and devices used for separating the

macromolecule from the mixture.

24. The method according to Claim 13 further including detecting errors in the operational input.

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25. The method according to Claim 13 wherein the separating includes (i) rough and fine filtering the mixture and (ii) operating a pump and at least one valve to cause pressure differentials across the filters.

- 10 26. An apparatus for preparing a macromolecule sample, comprising:
means for separating a macromolecule from a mixture also including
larger and smaller components; and
means for converting and executing operational input for controlling the
means for separating the macromolecule from the mixture.

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27. An apparatus for performing capillary electrophoresis, comprising:
an inlet chamber;
a capillary electrophoresis column with one end fixedly coupled to the
inlet chamber;

- 20 a liquid source coupled to the inlet chamber through an input valve to
supply a liquid sample in a controlled manner to the inlet chamber; and
a controller operatively coupled to the input valve and including
executable instructions to convert and execute operational input to control the
valve for providing a sample of the liquid source to the capillary electrophoresis
25 column.

28. The apparatus according to Claim 27 wherein the executable instructions are
compiled software.

29. The apparatus according to Claim 27 wherein the executable instructions are unchangeable.
30. The apparatus according to Claim 27 wherein the executable instructions
5 conform to a known industry standard.
31. The apparatus according to Claim 27 wherein the operational input includes declarative software instructions.
- 10 32. The apparatus according to Claim 27 wherein the executable instructions convert the operational input by interpreting program instructions.
33. The apparatus according to Claim 27 wherein the operational input is modifiable independent of the executable instructions.
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34. The apparatus according to Claim 27 wherein the controller includes an interface to receive the operational input from an external system.
35. The apparatus according to Claim 34 wherein the external system is coupled to
20 the controller via a network.
36. The apparatus according to Claim 27 wherein the executable instructions include correspondence between predetermined indicators in the operational input and the input valve.
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37. The apparatus according to Claim 27 wherein the executable instructions include instructions to detect errors in the operational input.
38. The apparatus according to Claim 27 wherein the inlet chamber is coupled to a

hydraulic system including rough and fine filters, a pump, and at least one valve.

- 5 39. A method for performing capillary electrophoresis comprising:
 providing a liquid source in fluid communication via an inlet chamber to
 an end of a capillary electrophoresis column fixedly coupled to the inlet
 chamber; and
 in response to converting and executing operational input, controlling
10 flow of the liquid source to the inlet chamber to provide a liquid sample in a
 controlled manner to the end of the capillary electrophoresis column.
40. The method according to Claim 39 wherein converting and executing the
 operational input includes executing executable instructions.
- 15 41. The method according to Claim 40 wherein the executable instructions are
 compiled software.
42. The method according to Claim 40 wherein the executable instructions are
20 unchangeable.
43. The method according to Claim 40 wherein the executable instructions conform
 to a known industry standard.
- 25 44. The method according to Claim 39 wherein the operational input includes
 declarative software instructions.
45. The method according to Claim 39 wherein converting the operational input
 includes interpreting program instructions.

46. The method according to Claim 39 wherein the converting and executing is performed by executable instructions, and the operational input is modifiable independent of the executable instructions.
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47. The method according to Claim 39 wherein converting and executing operational input includes receiving the operational input from an external system.
- 10 48. The method according to Claim 47 wherein receiving the operational input includes interfacing to the external system via a network.
49. The method according to Claim 39 further including determining correspondence between predetermined indicators in the operational input and a device used to control the flow of the liquid source.
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50. The method according to Claim 39 further including detecting errors in the operational input.
- 20 51. The method according to Claim 39 further including operating a hydraulic system producing the liquid source.
52. An apparatus for performing capillary electrophoresis comprising:
- 25 means for providing a liquid source in fluid communication via an inlet chamber to an end of a capillary electrophoresis column fixedly coupled to the inlet chamber;
- means for converting and executing operational input and responsively controlling flow of the liquid source to the inlet chamber to provide a liquid sample in a controlled manner to the end of the capillary electrophoresis

column; and

means for performing the capillary electrophoresis.

53. A method for distributing a system requiring approval by a regulatory
5 body, the method comprising:
validating executable instructions used to operate the system, the
executable instructions including instructions to convert and execute operational
input subject to independent validation;
obtaining the approval of the regulatory body for the system independent
10 of approval of the system with the operational input; and
distributing the approved system to a customer.
54. The method according to Claim 53 wherein the executable instructions are
compiled software.
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55. The method according to Claim 53 wherein the executable instructions are
unchangeable by the customer.
56. The method according to Claim 53 wherein the executable instructions conform
20 to a known industry standard.
57. The method according to Claim 53 wherein the regulatory body is a government
agency.
- 25 58. The method according to Claim 57 wherein the government agency is the Food
and Drug Administration (FDA).
59. The method according to Claim 57 wherein the government agency is the
Department of Defense (DOD).

60. The method according to Claim 53 wherein converting the operational input includes interpreting program instructions.
- 5 61. The method according to Claim 53 wherein the operational input includes declarative software instructions generated by the customer.
62. The method according to Claim 53 further including guaranteeing continued approval by the regulatory body of the system with the executable instructions
10 regardless of changes to the operational input.
63. The method according to Claim 53 wherein the system is used for preparing a sample of a macromolecule or performing electrophoresis on a sample of a macromolecule.
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64. The method according to Claim 63 wherein validating the executable instructions includes testing the system for a range of operational input reasonably expected to be applied by the customer to prepare or analyze the macromolecules.
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65. The method according to Claim 63 wherein the system includes a subset of valves, pumps, sensors, heating elements, cooling elements, or an electrophoresis column, and wherein validating the executable instructions includes verifying the executable instructions cause the subset of valves, pumps,
25 sensors, heating elements, cooling elements, or an electrophoresis column to operate according to the known industry standard.
66. The method according to Claim 63 further including allowing the customer (i) to custom-design declarative instructions used as the operational input to

customize operation of the system and (ii) to validate and obtain regulatory body approval of the system with the custom-designed declarative instructions without having to re-validate and obtain further regulatory body approval for the executable instructions.